Questions and answers: Good manufacturing practice

This page lists the European Medicines Agency's answers to frequently asked questions, as discussed and agreed by the Good Manufacturing Practice (GMP) / Good Distribution Practice (GDP) Inspectors Working Group.

Further questions and answers are published as the need arises. Individual questions and answers may be removed when the relevant GMP guidelines are updated.

Code

- H: applicable to human medicines
- V: applicable to veterinary medicines

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The supply chain for each active substance must be established back to the manufacture of the active substance starting materials. This should be documented and must be kept current. The risks associated with this supply chain should be formally documented. Control of each incoming consignment of active substance should include verification that it has been received from the approved supplier and approved manufacturer. The entire supply chain should be verified for a supplied batch periodically to establish a documented trail for the batch back to the manufacturer(s) of the active substance starting materials. The frequency of this verification should be based on risk.

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